IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC., Plaintiff, v. MSN LABORATORIES PRIVATE LIMITED and MSN PHARMACEUTICALS, INC., Defendants.	C.A. No. 22-cv-228 (RGA) (JLH) (Consolidated)

DEFENDANTS' RESPONSIVE POST-TRIAL FINDINGS OF FACT

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TABLE OF ABBREVIATIONS

Term	Definition
'015 patent	U.S. Patent No. 11,098,015 (JTX-003)
'349 patent	U.S. Patent No. 11,298,349 (JTX-004)
'439 patent	U.S. Patent No. 11,091,439 (JTX-001)
'440 patent	U.S. Patent No. 11,091,440 (JTX-002)
'643 patent	U.S. Patent No. 6,030,643 (PTX-243)
Ansel	Howard C. Ansel et al., PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS (7th ed. 1999) (DTX-363)
API	Active pharmaceutical ingredient
DTX	Defendants' Trial Exhibit
Exelixis	Plaintiff Exelixis, Inc.
Handbook	Raymond C. Rowe et al., Handbook of Pharmaceutical Excipients (5th ed. 2006) (DTX-275)
Lachman	Herbert A. Lieberman et al., PHARMACEUTICAL DOSAGE FORMS: TABLETS, VOL. 1 (2d. ed. 1989) (PTX-553)
Lahdenpää	Esa Lahdenpää et al., *Crushing Strength, Disintegration Time and Weight Variation of Tablets Compressed from Three Avicel® PH Grades and Their Mixtures*, 43 EURO. J. PHARMACEUTICS AND BIOPHARMACEUTICS 315 (1997) (DTX-355)
Jivraj	Mira Jivraj et al., *An Overview of the Different Excipients Useful for the Direct Compression of Tablets*, 3 PSTT 58 (2000) (DTX-344)
JTX	Joint Trial Exhibit
MSN	MSN Laboratories and MSN Pharmaceuticals
MSN Laboratories	Defendant MSN Laboratories Private Limited
MSN Pharmaceuticals	Defendant MSN Pharmaceuticals Inc.
POSA	Person of ordinary skill in the art
PTX	Plaintiff's Trial Exhibit
Swarbrick	James Swarbrick & James C. Boylan, ENCYCLOPEDIA OF PHARMACEUTICAL TECHNOLOGY (1991) (PTX-394)
USP	United States Pharmacopeia

TABLE OF WITNESSES

Witness	Live or By Deposition	Description
Dr. Maureen Donovan	Live	Dr. Donovan is MSN's expert in the field of pharmaceutics, including solid-dose drug formulation. She testified regarding the noninfringement and invalidity of the formulation of claim 3 of the '349 patent.
Dr. Salvatore Lepore	Live	Dr. Lepore is MSN's expert in the field of chemistry. He testified regarding the obviousness of the asserted claim 3 of the '349 patent.
Dr. Jonathan Steed	Live	Dr. Steed is MSN's expert in the formation, characterization, and use of pharmaceutical salts. Dr. Steed testified regarding the invalidity under 35 U.S.C. § 112 and obviousness-type double patenting of the asserted claims of the Malate Salt Patents.
Dr. Anthony Mega	Live	Dr. Mega is MSN's expert in the field of medical oncology. He testified in response to Exelixis' assertions of long-felt, unmet need and clinical success.
Dr. Robert DeForest McDuff	Live	Dr. McDuff is MSN's expert in evaluating economics of the pharmaceutical industry. He testified in response to Exelixis' assertion of commercial success.
Dr. Jo Ann Wilson	By Deposition	Dr. Wilson is a named inventor of the '349 patent.
Dr. Peter Lamb	By Deposition	Dr. Lamb is a named inventor of the Malate Salt Patents.
Dr. Khalid Shah	Live	Dr. Shah is a corporate representative of Exelixis and a named inventor of the '349 patent.
Dr. David MacMillan	Live	Dr. MacMillan is Exelixis' expert in the field of organic and medicinal chemistry. He testified regarding expectation of success of recrystallization with respect to claim 3 of the '349 patent.
Dr. Bernhardt Trout	Live	Dr. Trout is Exelixis' expert in the field of pharmaceutical development and manufacturing, including with respect to crystallization of pharmaceutical salts. Dr. Trout testified as to the

Witness	Live or By Deposition	Description
		purported validity of the asserted claims of the Malate Salt Patents, particularly as to written description under 35 U.S.C. § 112 and obvious-type double patenting.
Dr. Allan Myerson	Live	Dr. Myerson is Exelixis' expert in the fields of separation and purification methods, crystallization, pharmaceutical formulation, and pharmaceutical manufacturing. Dr. Myerson testified regarding the purported nonobviousness of the '349 patent.
Dr. John Koleng	Live	Dr. Koleng is Exelixis' expert in pharmaceutical formulation. Dr. Koleng testified as to infringement of the asserted claim 3 of the '349 patent and purported nonobviousness of the Malate Salt Patents.
Dr. Daniel James George	Live	Dr. George is Exelixis' expert in the field of treatment of cancer, including renal cell carcinoma. He testified regarding purported clinical success, and long-felt, unmet need.
Michael Tate	Live	Mr. Tate is Exelixis' expert in the field of economic analysis as it pertains to commercial success. He testified regarding purported commercial success.

I. TECHNICAL BACKGROUND OF THE '349 PATENT

227. In pharmaceutics, powder "flow" is the movement of a powder mixture from one position to another, such as through tablet manufacturing equipment. Tr. 188:21-189:6 (Donovan). Each ingredient has its own flow properties and contributes to a powder mixture's overall flow properties. Tr. 189:21-190:25, 191:6-11 (Donovan); Tr. 146:19-147:14 (Koleng). Particle size and shape can impact flow properties. Tr. 189:7-191:5 (Donovan); DDX(Donovan)-6.

228. The measured bulk and tapped density of a powder sample can be used to calculate its Hausner ratio (ρtapped/ρbulk) and Carr Index (100 x ((ρtapped – ρbulk)/ρtapped)), two common methods reported in USP to characterize powder flow. DTX-358.3-4; Tr. 191:12-24 (Donovan); Tr. 129:14-22, 131:3-7 (Koleng). A decrease in Hausner ratio and Carr Index values can potentially reflect an improvement in flow character. DTX-358.3; Tr. 131:11-22 (Koleng).

229. A formulator can use granulation and excipient selection, among other things, to improve the flow properties of a poorly flowing API. Tr. 192:11-21, 194:3-10 (Donovan).

230. Wet granulation of a powder blend can improve the mixture's overall flow properties by forming aggregates, or granules, of API and other powder ingredients that are more uniform in size and shape than the API alone. Tr. 192:25-193:24 (Donovan); Tr. 133:19-21 (Koleng); Tr. 609:22-610:23 (Shah); DDX(Donovan)-7. Use of granulation techniques can resolve an API's poor flow properties. Tr. 193:25-194:2 (Donovan).

231. The addition of a diluent can improve a powder mixture's overall dissolution, disintegration, and flow properties. Tr. 150:10-24 (Koleng). A common definition of diluent is "[i]nert substances used as fillers to create the desired bulk, flow properties, and compression characteristics in the preparation of tablets and capsules." DTX-363.35; Tr. 194:11-195:10 (Donovan). A diluent can improve flow by bulking up the mixture, reducing the chance of poorly flowing API and other excipients interacting. Tr. 195:11-196:7 (Donovan); DDX(Donovan)-8.

232. The addition of a glidant can improve a powder mixture's overall flow properties. Tr. 198:20-23, 254:19-22 (Donovan). Glidants improve flowability through five mechanisms reported in the prior art: (1) coating/adherence; (2) adsorbing fine particles; (3) reducing electrostatic forces; (4) adsorbing environmental gases; and (5) reducing van der Waals forces. DTX-134.33-34; PTX-553.136; Tr. 199:11-200:12 (Donovan); Tr. 165:15-21 (Koleng).

II. NONINFRINGEMENT OF THE '349 PATENT

A. MSN's ANDA identifies GRASTAR as a diluent.

233. The application that issued as the '349 patent was published on June 3, 2021. JTX-4.2. MSN's ANDA was submitted on August 16, 2019. DTX-160.1; Tr. 168:19-169:16 (Koleng).

234. MSN's ANDA does not identify any excipient to be a glidant in MSN's tablets. DTX-231.2, 4; Tr. 202:18-203:1 (Donovan). MSN's ANDA identifies GRASTAR as a diluent in MSN's tablets. DTX-231.2, 4; Tr. 201:16-20, 202:5-17 (Donovan); Tr. 164:22-24 (Koleng).

235. The 9.71% concentration at which GRASTAR is used in MSN's tablets (DTX-231.2) is consistent with amounts reported by the scientific literature for use of diluents (*see* Tr. 201:21-202:4 (Donovan); DTX-275.754 (diluent at 5-75%), 790 (diluent at 5-30%)) and also disintegrants (*see* DTX-275:754 (disintegrant at 5-10%); PTX-553.129 (disintegrant at 5-10%)).

B. GRASTAR pregelatinized corn starch is not a glidant.

236. GRASTAR is a granulated, or pregelatinized, corn starch. DTX-296.2.

237. The GRASTAR manufacturer identifies the ingredient's potential functions as a filler, a binder, or an oral disintegrant. DTX-296.2. A POSA would understand that oral disintegrants can also serve as disintegrants in traditional tablets. Tr. 204:19-205:1 (Donovan).

238. GRASTAR has "good flowability" and "excellent" disintegration properties, but the manufacturer does not identify it as a glidant. DTX-296.2; Tr. 164:16-21 (Koleng).

239. The Handbook identifies binder, diluent, and disintegrant as potential functions of

pregelatinized starch, but not glidant. DTX-275.754; Tr. 205:20-206:15 (Donovan). By contrast, the Handbook identifies binder, diluent, disintegrant, and glidant as potential functions for unmodified starch. DTX-275.748; Tr. 206:16-207:5 (Donovan). This is consistent with the scientific literature's identification of functions for those ingredients. Tr. 207:10-14 (Donovan); *see also, e.g.*, PTX-394.10, 44 (pregelatinized starch (Starch 1500) described as filler, binder, and disintegrant and not listed in table of glidants).

240. Lachman is the only textbook Dr. Koleng identified supporting his opinion that pregelatinized starch is a glidant. Tr. 160:25-161:4 (Koleng). It published about 30 years before MSN's ANDA submission. Tr. 161:10-15 (Koleng); DTX-160.1 It does not provide any examples of any formulations using pregelatinized starch as a glidant. Tr. 207:15-208:6 (Donovan).

241. The '643 patent is the only patent Dr. Koleng identified supporting his opinion that pregelatinized starch is a glidant. Tr. 157:18-23 (Koleng). It issued about 20 years before MSN's ANDA submission. Tr. 157:24-158:4 (Koleng); DTX-160.1. It also lists pregelatinized corn starch as a potential filler, binder, and anti-adherent for the claimed formulation. PTX-243.7, 9; Tr. 158:5-159:13 (Koleng). It does not provide any examples of formulations using pregelatinized starch as a glidant. Tr. 160:5-11 (Koleng); Tr. 207:15-208:6 (Donovan).

C. MSN added GRASTAR to function as a diluent, not a glidant.

1. MSN used wet granulation to improve the API's flow properties.

242. To improve the API's poor flow properties, MSN used wet granulation to prepare its tablets. DTX-215.34 ("[I]t is evident that the API exhibits poor flow properties. Hence the process of choice was wet granulation over direct compression."); Tr. 209:8-15 (Donovan).

243. Wet granulation improved the flowability of the granules over the dry mix. Tr. 133:22-134:1 (Koleng). The use of wet granulation addressed MSN's concern with the API's poor flow properties—no other MSN development documents or subsequent experiments

indicated any concern with flow properties or consideration of formulation changes to add a glidant to further improve flow properties of the powder blend. Tr. 209:16-25, 216:20-217:6 (Donovan).

2. GRASTAR was added as a diluent to adjust disintegration and dissolution properties.

244. MSN documented its formulation development work for its tablets in Laboratory Notebook No. 252. DTX-196; Tr. 134:22-135:3 (Koleng). Dr. Koleng relied on data reported in this notebook in forming his infringement opinions. Tr. 129:9-13, 135:4-7 (Koleng).

245. During development, MSN initially used 30 mg unmodified corn starch (maize starch B) in the extra-granular layer of its formulation, shown in prototype Batch No. 252/023. DTX-196.46; Tr. 134:11-14 (Koleng); Tr. 210:1-21 (Donovan). MSN later replaced maize starch B with 30 mg GRASTAR granulated corn starch, as shown in prototype Batch No. 252/044. DTX-196.84; Tr. 134:15-21 (Koleng); Tr. 210:22-211:7 (Donovan). There are no other differences between the two formulations. DTX-196.46, 84; Tr. 135:19-136:6 (Koleng); DDX(Koleng)-2.

246. MSN's excipient changes during formulation development, including the substitution of maize starch B with GRASTAR, were focused on the disintegration and dissolution properties of its tablets. Tr. 211:11-16, 212:1-5 (Donovan).

247. As further examples, MSN evaluated and adjusted the amount of intra-granular croscarmellose sodium disintegrant that would produce a dissolution profile matching CABOMETYX. DTX-215.38-47; Tr. 212:6-213:25 (Donovan); DDX(Donovan)-10. MSN also evaluated the amount of extra-granular croscarmellose sodium disintegrant (DTX-215.53-55), hydroxypropyl cellulose binder (DTX-215.56-58), and magnesium stearate lubricant (DTX-215.61-63) that would match CABOMETYX's dissolution profile.

248. MSN also evaluated the amount of GRASTAR that would match CABOMETYX's dissolution profile. DTX-215.58-60; Tr. 214:5-216:24 (Donovan); Tr. 63:17-64:5

(Nithiyanandam). MSN found there were "no significant difference[s]" in dissolution profile for prototypes with 6.7%, 9.7%, and 12.7% GRASTAR. DTX-215.60. From this data, a POSA would not conclude GRASTAR has *no* effect on the formulation's dissolution profile, including because there is no data for a prototype with 0% GRASTAR. Tr. 215:20-216:13 (Donovan).

3. Testing data shows the addition of GRASTAR did not improve flow.

249. There is no evidence that GRASTAR improves flow in MSN's tablets. Tr. 228:4-7 (Donovan). Adding GRASTAR did not result in any meaningful improvement in the flow properties of Batch No. 252/044 compared to Batch No. 252/023. Tr. 211:17-25 (Donovan).

250. For Batch Nos. 252/023 and 252/044, the measured bulk and tapped density values, and the Hausner ratio and Carr Index calculated from those density measurements, were recorded in MSN's Laboratory Notebook as follows (DDX(Koleng)-2; Tr. 135:15-137:3 (Koleng)):

Batch No. 252/023		Batch No.252/044	
Bulk density	0.515 g/mL	Bulk density	0.541
Tapped density	0.708	Tapped density	0.825
Carr index	27.7	Carr index	25.92
H.R.	1.375	H.R.	1.350

251. USP would characterize the flow character of both Batch Nos. 252/023 and 252/044 as "poor" based on the recorded Hausner ratio and Carr Index. DTX-358-4; Tr. 137:5-20 (Koleng).

252. The Hausner ratio and Carr Index values recorded for Batch No. 252/044 reflect a calculation error. Tr. 139:5-8 (Koleng). The correctly calculated values using the measured bulk and tapped density measurements are below (DDX(Koleng)-4; Tr. 139:19-140:9 (Koleng)):

Batch No. 252/023		Batch No.252/044	
Bulk density	0.515 g/mL	Bulk density	0.541
Tapped density	0.708	Tapped density	0.825
Carr index	27.7	Carr index	~~25.92~~ 34.42
H.R.	1.375	H.R.	~~1.350~~ 1.52

253. The correctly calculated Hausner ratio and Carr Index from the measured bulk and

tapped density measurements show a directional reduction in flow character for Batch No. 252/044 compared to Batch No. 252/023. Tr. 140:24-141:4 (Koleng).

254. Dr. Koleng did not opine that maize starch B in Batch No. 252/023 functions as a glidant. Tr. 141:5-9 (Koleng).

D. Even if GRASTAR improved the flow properties of MSN's tablets, that would not make it a glidant.

1. Diluents can have a positive impact on overall powder flow properties.

255. A POSA would not consider *every* excipient that has any positive impact on powder flow to be a glidant. Tr. 198:24-199:3, 254:23-255:2 (Donovan). No scientific literature states that a glidant is the *only* excipient that can have a positive effect on flow, or that *anything* having a positive effect on a flow is a glidant. Tr. 199:4-7, 254:23-255:2 (Donovan).

256. Indeed, scientific literature gives guidance on how the selection of a filler (without also being a glidant) can affect overall flow properties of a powder blend. Tr. 196:8-11 (Donovan).

257. For example, Lahdenpää describes various tablet characteristics, including flow properties, for three different grades of microcrystalline cellulose ("MCC"). Tr. 196:12-20 (Donovan); DTX-355.1, 6. MCC is frequently used as a filler. Tr. 197:4-5 (Donovan); Tr. 153:9-11 (Koleng). Lahdenpää does not refer to any grade of MCC as a glidant (Tr. 197:18-21 (Donovan)), and while Dr. Koleng has personally used MCC, he has never used it as a glidant in any of the hundreds of formulations he has helped prepare (Tr. 153:9-15, 154:11-14 (Koleng)).

258. Jivraj reports on the functionality of certain fillers. DTX-344.1, 2-3, 5; Tr. 197:22-198:12 (Donovan). It states that MCC's "limitation of poor flow can be offset by mixing with another filler with good flowability, such as α-lactose monohydrate." DTX-344.3. Lactose is a common diluent (Tr. 154:5-6 (Koleng)), and Dr. Koleng has never used it as a glidant in any formulation (Tr. 154:7-10 (Koleng)). Jivraj further reports that granulated lactitol has "good flow

properties, and formulations containing granulated lactitol do not require a glidant." DTX-344.5.

2. There is no evidence GRASTAR improves flow in MSN's tablets through any reported glidant mechanism.

259. There is no evidence that GRASTAR operates to improve flow through any of the five glidant mechanisms described in the scientific literature. Tr. 217:25-218:3 (Donovan).

260. A glidant can improve flow by coating or adhering to the surface of larger host particles, which reduces friction between them. Tr. 218:5-15 (Donovan); Tr. 123:6-11 (Koleng). It is the most common glidant mechanism. Tr. 200:13-21 (Donovan); Tr. 123:6-11 (Koleng).

261. GRASTAR's average particle size is 81.58µ (microns). DTX-296.3; Tr. 205:3-8 (Donovan); Tr. 166:7-9 (Koleng). MSN's wet granulation produces granules of API and intra-granular components that are approximately 150µ. Tr. 218:24-219:23 (Donovan); Tr. 166:13-20 (Koleng). Particles the size of GRASTAR will not act as a glidant by adhering to the granules in MSN's tablets due to their similarity in size. Tr. 205:9-16, 218:5-219:23 (Donovan); DDX(Donovan)-11. There is no electron microscope or other data showing GRASTAR adheres to the surface of other particles in MSN's powder blend. Tr. 166:21-25 (Koleng).

262. A glidant can improve flow by adsorbing very small, fine particles that can impede flow. Tr. 219:24-220:11 (Donovan); DDX(Donovan)-12; Tr. 118:16-119:1 (Koleng).

263. The particles Dr. Koleng characterizes as "fines" in MSN's powder blend are less than 150µ, but he cannot say how much less. Tr. 168:2-6 (Koleng); Tr. 220:16-221:10 (Donovan). Particles the size of GRASTAR will not act as a glidant by adsorbing the so-called "fines" in MSN's tablets due to their similarity in size. Tr. 220:16-221:10 (Donovan); DDX(Donovan)-12.

264. The GRASTAR manufacturer reports that the flowability of jet-milled, micronized fenofibrate can be improved by blending it with GRASTAR, which "may be because most of the small fenofibrate particles can preferably adhere to the void space of GRASTAR particles." PTX-

447.1-2. However, a POSA would expect jet-milled, micronized fenofibrate to be smaller than 10µ (Tr. 222:4-11 (Donovan)), and no more than 30µ (Tr. 167:21-168:1 (Koleng)). The GRASTAR document related to fenofibrate thus has no relevance to whether GRASTAR acts as a glidant by adsorbing "fines" in the MSN tablets—the sizes are not comparable. Tr. 222:12-22 (Donovan).

265. A glidant can improve flow by dispersing electrostatic charges that cause friction between particles and impede flow. Tr. 223:1-10 (Donovan); Tr. 118:2-6 (Koleng). GRASTAR does not act as a glidant through this mechanism in MSN's tablets—there is no evidence of powder sticking to vessels or experiments performed by MSN to resolve electrostatic friction. Tr. 223:1-10 (Donovan); Tr. 170:6-10 (Koleng).

266. A glidant can improve flow by adsorbing gases, such as air or water vapor, which can cause flow resistance. Tr. 122:2-6 (Koleng). GRASTAR does not act as a glidant through this mechanism in MSN's tablets—there is no evidence of poor wetting or gas buildup in the powder blend, or experiments performed by MSN to change dissolution methodologies or its formulation to disperse gas. Tr. 223:11-23 (Donovan); Tr. 170:20-23 (Koleng).

267. A glidant can improve flow by reducing van der Waals forces, which are atomic-level interactions between electron clouds of atoms on the surface of particles. Tr. 223:24-224:17, 248:3-15 (Donovan). GRASTAR does not act as a glidant through this mechanism in MSN's tablets—there is not enough surface area in contact between the large particles in MSN's tablets for van der Waals forces to hold them together. Tr. 223:24-224:17, 248:3-15 (Donovan).

E. MSN documents do not prove GRASTAR is a glidant in MSN's tablets.

268. GRASTAR's addition at the pre-lubrication stage of manufacturing does not make it a glidant. Tr. 228:19-229:4 (Donovan). Disintegrants (including one in MSN's tablets), fillers, and other ingredients can also be added then. Tr. 229:5-10 (Donovan); Tr. 142:9-22 (Koleng).

269. MSN's "Justification for Microbial Method Validation" contains a general

statement that "[s]tarch [is] used in pharmaceutical industry for a wide variety of reasons, such as an excipient in tablet and capsule as a diluent, as a glidant or as a binder." PTX-724.2. This is a true statement about how certain starches *may* be used in the pharmaceutical industry, depending on the formulation. Tr. 226:2-12 (Donovan). The document does not have anything to do with measuring or evaluating flow properties in unmodified corn starch, GRASTAR granulated corn starch, or MSN's ANDA products. Tr. 225:23-226:1 (Donovan).

270. During its "Initial Risk Assessment," MSN prepared a table describing its tablet ingredients. DTX-215.34. This assessment is usually performed before formulation development starts to direct and prioritize evaluating a formulation. Tr. 227:2-9 (Donovan). MSN stated that Granulated Corn Starch "is used as a diluent in minimal concentration and it enhances the flowability of the granules." DTX-215.36. This was written based on the scientific literature before MSN's formulation experiments. Tr. 61:17-62:9 (Nithiyanandam); Tr. 227:18-228:3 (Donovan).

271. In the table, MSN also stated that the magnesium stearate in MSN's formulation "enhances the flow properties." DTX-215.36. Dr. Koleng agreed that magnesium stearate is a lubricant in MSN's tablets and did not opine that it was a glidant. Tr. 145:8-19 (Koleng). MSN also stated that the lactose monohydrate in MSN's formulation "can impact the flow properties of the blend." DTX-215.35. Dr. Koleng agreed that lactose monohydrate is a diluent in MSN's tablets and did not opine that it was a glidant. Tr. 145:21-146:15 (Koleng).

272. In MSN's formulation development trial titled "Optimization of level of Granulated Corn Starch (Diluent)," there was no testing performed on flow properties of the three prototype batches with varying GRASTAR amounts. DTX-215.58-60; Tr. 214:25-215:8 (Donovan). MSN's statement that "[t]he level of Granulated corn Starch plays an important role in flow characteristics" was based on the scientific literature. Tr. 62:21-64:5 (Nithiyanandam).

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